

## **REMARKS**

### **Summary of the Office Action**

In the Office Action, Examiner:

- 1) Rejected Claims 1-4, 8, 9, 12, 13, 15-19, and 21 under 35 U.S.C. § 103(a) as being unpatentable over 5,480,410 ("Cuschieri et al.") in view of U.S. Patent No. 4,802,474 ("Beevers");
- 2) Rejected Claims 6, 7, 10, and 11 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of Beevers and in further view of U.S. Patent No. 4,175,563 ("Arenberg et al.");
- 3) Rejected Claims 14 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of Beevers and in further view of U.S. Patent No. 3,618,606 ("Brown et al."); and
- 4) Rejected Claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Cuschieri et al. in view of Beevers and in further view of U.S. Patent No. 5,976,118 ("Steer").

By this Reply, Claims 2-4 are cancelled, and Claims 1, 6-9, 12-16, and 18-20 are amended. Upon entry of the amendments, Claims 1 and 6-22 are pending.

### **Claim Amendments**

In order to overcome the claim rejections raised by Examiner and for clarification of the claimed features, an amended set of claims is submitted herewith.

Claim 1 has been amended by the introduction of features from previous claims 2, 3 and 4, together with the feature that the apertures, in the first and second layers respectively, are oriented in substantially the same direction (based on previous claim 7).

Claim 1, therefore, is directed to a lesion or fistula bag having the following features:

- a) a first chamber, which can be sealed and closed,
- b) a second chamber, which is isolated from the first chamber, for providing access to a wound,
- c) attachment means for fixing the lesion bag to the skin of a patient over the wound, so that the wound can be accessed through the second chamber,

- d) a flexible partition, serving to isolate the second chamber from the first chamber and comprising first and second adjacent layers of material, and
- e) a valve in the flexible partition, comprising portions of the first and second layers and including a first aperture in the first layer and a second aperture in the second layer, wherein the first and second apertures are oriented in substantially the same direction and are offset from one another.

The important aspect of Applicant's fistula bag is that, when it is attached to the skin of a patient over a wound and in the closed state, two closed and sealed chambers isolate the wound from the surrounding atmosphere. As a result, the wound is fully protected from the ingress of contaminants or products that might cause infection. At the same time, a secure seal is provided against any leakage or discharge from the wound. It will be appreciated that this is very important in the field of medical treatment, for example in a hospital setting, both for the health and protection of the patient and for the health and protection of medical staff and other patients.

The references do not disclose all of the limitations of claim 1. Examiner based his rejection of the claims primarily on Cuschieri, maintaining in Paragraph 12 of the Office Action that Cuschieri discloses two chambers A and B, and therefore discloses the two chambers of the present invention. However, Cuschieri does not disclose the chambers of claim 1. In Paragraph 5 of the Office Action, Examiner acknowledged that the definition of the term "chamber" is "an enclosed space." "Enclosed" means just that, i.e. a space which is closed and not open. The only enclosed space provided by Cuschieri is that inside the enclosure 2. In other words, Cuschieri discloses a single chamber (inside the enclosure 2) and not two chambers.

More particularly, Examiner argued that the two sides of the iris valve 11 constitute two chambers both of which are inside the enclosure 2. However, this distorts the disclosure of Cuschieri. Figures 3a to 3d of Cuschieri describe the manner in which each iris valve 11 is formed during the manufacture of the Cuschieri device. Thus, although the iris valve 11 begins as a tube 12, and the twisting of the ends of the tube 12 in opposite directions produces two open cavities A and B, this is not comparable to the two chambers of the present invention. First, this is not the final state of the iris valve 11, to be found in the finished Cuschieri product, but rather an intermediate step. Secondly, the two cavities A and B are not closed (i.e. "enclosed"). Thirdly, only one and not both of these cavities A, B, when the tube 12 is formed

into the final iris valve 11, lies on the inside of the enclosure 2. Actually, the iris valve 11, by the time it is attached to the enclosure 2, has already acquired the flat form shown in Figure 3d, in which it provides no chamber or enclosure at all but only a flat circular face on each side of the valve, openable in the center to provide an access opening 5.

It appears Examiner argued that, according to Cuschieri, the iris valve 11 both provides two enclosed chambers and also provides a flexible partition with a valve separating the two chambers, when actually Cuschieri simply describes the iris valve 11 only as a valve.

Further, assuming for the sake of argument that Cuschieri discloses in the iris valve 11 a flexible partition comprising first and second adjacent layers of material, the nature of this valve does not anticipate the valve of claim 1 because such iris valve 11 does not include "a first aperture in a first layer and a second aperture in a second layer, wherein the first and second apertures are oriented in substantially the same direction and are offset from one another."

As for combining Cuschieri with Beevers, in response to the Office Action of August 18, 2008, Applicant demonstrated that Cuschieri and Beevers are not combinable. Applicant will not repeat those arguments, except to say that the same remain applicable. With that being acknowledged, Applicant supplements those arguments as follows.

First, in many instances in the Office Action Examiner simply stated that "it would be obvious to one skilled in the art" but without substantiating these allegations. To the extent that Examiner wishes to maintain allegations based on common general knowledge, he is asked to provide specific prior art references to demonstrate and substantiate his views. In the alternative, Applicant requests an affidavit from Examiner attesting to such personal knowledge. Examiner is reminded that pursuant to 37 C.F.R. § 1.104(d)(2) "when a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons."

Secondly, Examiner's arguments relating to Cuschieri are puzzling. On one hand Examiner maintained that one side of the iris valve 11 constituting chamber A is fully capable of being closed, but on the other hand Examiner argued that the bag 2 of Cuschieri has a closable entrance 5 (which incidentally is provided by the iris valve 11). Therefore, it is not at all clear

which portion of Cuschieri Examiner is defining as being the counterpart of Applicant's first chamber including a closable entrance having a closure for sealingly closing the closable entrance. In any event, Examiner acknowledged on page 5 lines 1 and 2 of the Office Action, that "Cuschieri does not expressly disclose the fistula isolating bag comprising a closure for the closable entrance." Examiner then referred to Beevers and the protective cover 11 described therein as such a closure.

Beevers, however, discloses a tracheotomy tube having a protective cover, and describes the protective cover as the whole of the device 10 shown in Figure 1. Consequently, according to Beevers, the protective cover comprises a collar 11 frictionally engaging the outside end of a tracheal tube 15, the collar 11 having a vent flange 12, cage bars 14, and an end plate 19 for the specific purpose of permitting the introduction of a standardized aspirating tube while keeping out foreign objects. Accordingly, Beevers requires a tracheotomy tube for receiving the collar 11, and it specifically teaches away from a closure, especially from a closure for sealingly closing a closable entrance. Furthermore, Beevers is not in anyway concerned with the prevention of air access to the tracheotomy tube but only with the keeping out of physical foreign objects.

Therefore, it is submitted that it would not be obvious to employ the collar 11 of Beevers in association with the bag 2 of Cuschieri, because the bag 2 of Cuschieri lacks any tube for receiving the collar 11 of Beevers. Even if one was to apply the collar 11 of Beevers to the bag 2 of Cuschieri, the result would not be a closable entrance, because Beevers' collar 11 specifically includes a vent flange 12 with a cage 14 attached. In addition, the provision of the cage 14, 19 attached to the vent flange 12 ensures that the cover 10 cannot be sealed, and therefore a combination of Cuschieri and Beevers does not yield a chamber having a closable entrance, together with a closure for sealingly closing the closable entrance.

Neither Cuschieri nor Beevers discloses a flexible partition, dividing first and second chambers from one another and including a valve comprising first and second layers of material containing respectively first and second apertures, which are oriented substantially in the same direction and are offset from one another. Should Examiner continue to maintain that the specific valve construction, just indicated, is obvious in the face of Cuschieri in view of Beevers and common general knowledge, he is asked to substantiate this by providing specific prior art

references which clearly demonstrate this. Again, in the alternative, Applicant requests an affidavit from Examiner attesting to such personal knowledge. Examiner is reminded that pursuant to 37 C.F.R. § 1.104(d)(2) “when a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the applicant and other persons.”

Examiner cited Arenberg et al. in support of the argument that it is obvious to provide a valve in the form of parallel slits (see paragraph 26 of the Office Action). Arenberg et al., however, discloses a biological drainage shunt comprising a rigid tube 1, a flexible extension tube 10 at one end of the tube 1, and a generally rigid tubular housing surrounding the extension tube 10. At the free end of the extension tube 10 is provided a plug 20 having at least one slit 21 therein. As shown in Figures 4 and 7, the plug 20 contains a pair of slits 21 intersecting at right angles. Whether or not it would have been obvious to modify the closure 10 of Beevers with the slit valve 20 of Arenberg et al, the result is not the valve according to Applicant’s claim 1, because the result is not first and second apertures provided in sheet material, and provided in first and second layers of sheet material at that, and the result is not first and second apertures oriented in substantially the same direction but offset from one another.

In paragraph 28 of the Office Action, Examiner argued that the positioning of the slits 21 of Arenberg et al parallel to one another is merely a design choice, Examiner is going far beyond the teachings of the reference and employing hindsight reasoning. It is not merely the orientation of Applicant’s apertures but the nature of the valve itself that is not disclosed in the combination Cuschieri/Beevers/Arenberg. Applicant’s valve is flexible; it is formed in two layers of sheet material; it comprises an aperture in each such layer; and the apertures are oriented in the same direction and are offset from one another. The cited references contain no disclosure of such a sheet material valve, and especially no disclosure of Applicant’s arrangement of apertures that permits the valve to close when it is required to isolate the first and second chambers from one another, and yet permits access, by pushing a hand through the valve, when the wound is to be accessed through the second chamber.

**CONCLUSION**

In view of the foregoing Amendments and Remarks, Applicant respectfully requests the Examiner to reconsider the rejections and allow Applicant's claims as amended. If deficiencies remain, the Examiner may contact the undersigned to facilitate allowance of this case.

Respectfully submitted,

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